- 14 -

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1.   A method of diagnosing and/or determining the risk of developing gastric cancer

in a subject with a *Helicobacter* infection, including:

    a) determination of IgG2 anti-*H. pylori* antibody level in the subject;

    b) comparison of the IgG2 anti-*H. pylori* antibody level with a predetermined

control IgG2 anti-*H. pylori* antibody level, wherein a reduction in the level of IgG2 anti-

H. pylori antibody in the subject compared to the control indicates the presence and/or

increased risk of developing gastric cancer.

2.   A method of diagnosing and/or determining the risk of developing gastric cancer

in a subject with a *Helicobacter* infection, including:

    a) determination of γIFN level in the subject;

    b) comparison of the γIFN level with a predetermined control γIFN level, wherein

a reduction in the level of γIFN in the subject compared to the control indicates the

presence and/or increased risk of developing gastric cancer.

3.   A method of diagnosing and/or determining the risk of developing gastric cancer

in a subject with a *Helicobacter* infection, including:

    a) determination of IL-4 level in the subject;

    b) comparison of the IL-4 level with a predetermined control IL-4 level, wherein

an elevation in the level of IL-4 in the subject compared to the control indicates the

presence and/or increased risk of developing gastric cancer.

4.   A method of diagnosing and/or determining the risk of developing gastric cancer

in a subject with a *Helicobacter* infection, including a combination of a method

- 15 -

according to claim 1 and/or a method according to claim 2 and/or a method according to

claim 3.

5.   A method of diagnosing and/or determining the risk of developing gastric cancer

in a subject with a *Helicobacter* infection, including a combination of a method

5   according to claim 2 and a method according to claim 3.

6.   A method according to any one of claims 1 to 6 wherein the *Helicobacter* infection

is a *Helicobacter pylori* infection.

7.   A method according to any one of claims 1 to 7 wherein the IgG2 anti-*H. pylori*

antibody, γIFN and/or IL-4 levels are determined by detection of the levels in a sample

10   of biological fluid.

8.   A method according to claim 7 wherein the biological fluid is blood.

9.   A method according to claim 7 wherein the biological fluid is saliva.

10.   A method according to claim 7 wherein the biological fluid is gastric fluid.

11.   A method according to any one of claims 1 to 10 wherein the measurement of

15   IgG2 anti-*H. pylori* antibody, γINF and/or IL-4 either simultaneously provides, or can be

performed simultaneously with, a method which provides an indication of *H. pylori*

status.

12.   A method according to any one of claims 1 to 11 wherein the IgG2 anti-*H. pylori*

antibody, γIFN and/or IL-4 are detected by a near-subject assay.

20   13.   A method according to any one of claims 1 to 11 wherein the assay is a laboratory-

based test.

14.   A method according to claim 12 or claim 13 wherein the assay is an antibody

assay.

- 16 -

15.   A method according to claim 14 wherein the antibody assay is an ELISA.

16.   A method of predicting the risk of, and/or diagnosing, gastric cancer in a subject

having a *Helicobacter* infection by

        a)   determining the frequency of IgG2 anti-*H.pylori* antibody- and/or γIFN- and/or

IL-4-producing cells in the subject's blood; and

        b)   comparison of the frequency of IgG2 anti-*H.pylori* antibody- and/or γIFN-

and/or IL-4-producing cells in the subject's blood with a predetermined control level,

wherein a reduction in the level of IgG2 anti-*H.pylori* antibody- and/or γIFN-producing

cells and/or an elevation in IL-4-producing cells in the subject's blood indicates the

presence and/or increased risk of developing gastric cancer.

17.   A method according to claim 16 wherein the blood is purified to provide an

enriched white blood cell population.

18.   A method according to claim 17 wherein the white blood cell population is further

fractionated to obtain specific cell populations.

19.   A method according to any one of claims 16 to 18 wherein the IgG2 anti-*H.pylori*

antibody- and/or γIFN- and/or IL-4-producing cells are stimulated with *H. pylori* antigen

prior to measurement of IgG2 anti-*H.pylori* antibody and/or γIFN and/or IL-4.

20.   A method of predicting the risk of, and/or diagnosing, gastric cancer in a subject

having a *Helicobacter* infection by

        a)   determining the frequency of IgG2 anti-*H.pylori* antibody and/or γIFN and/or

IL-4-producing cells in the subject's gastric mucosa; and

        b)   comparison of the frequency of IgG2 anti-*H.pylori* antibody and/or γIFN and/or

IL-4-producing cells in the subject's gastric mucosa with a predetermined control level,

wherein a reduction in the level of IgG2 anti-*H.pylori* antibody- and/or γIFN-producing cells and/or an elevation in IL-4-producing cells in the subject's gastric mucosa indicates the presence and/or increased risk of developing gastric cancer.

21.   A method according to claim 20 wherein the cells are derived from a biopsy sample.

22.   A method according to claim 20 or claim 21 wherein of IgG2 anti-*H.pylori* antibody and/or γIFN and/or IL-4-producing cells are detected by flow cytometry.